K011561

NOV 2 0 2001

Optikem International, Incorporated

2172 South Jason Street Denver, Colorado 80223 USA

510(K) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

PHONE:
303-936-1137
800-525-1752

FAX:
303-936-7320

E-Mail
OptikemInt
@AOL.COM

1. Submitter's Name

   Optikem International, Inc.
   2172 South Jason Street
   Denver, CO 80223

   Telephone: 303-936-1137
   FAX: 303-936-7320

2. Contact Person

   Sally Cook
   President

3. Date Summary was Prepared:

   May 8, 2001

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

4. Name of Device

Trade Name: Sereine Extra Strength Daily Cleaner

Common Name: Daily Cleaner for Contact Lenses

Classification Name: Contact Lens Cleaner

5. Legally Marketed Device to Which Equivalence is Claimed:

MiraFlow Extra Strength Daily Cleaner, CIBA Vision Corporation, Duluth, GA 30155.

6. Description of Device:

Sereine Extra Strength Daily Cleaner is a sterile, viscous, aqueous solution with an alkaline pH. The cleaner contains no added preservatives. The cleaner contains an amphoteric surfactant to aid in the removal of proteins, lipids and other debris which accumulate on contact lenses during wear. The cleaner is not meant for use in the eye and must be thoroughly rinsed from the lenses.

Sereine Extra Strength Daily Cleaner is packaged in a 1 FL OZ plastic bottle (polyethylene) with red dropper tip (polyethylene) and white over-cap (polypropylene). It has an outside cardboard carton. It has an expiration date of two years from the date of bottling.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

7. Intended Use of the Device:

Sereine Extra Strength Daily Cleaner is a daily cleaner for use in removing protein, lipids and other accumulated debris which collects on contact lenses during wear.

Sereine Extra Strength Daily Cleaner is intended for use with all soft (hydrophilic) lenses and hard (PMMA) lenses on a daily basis. The cleaner is for use on lenses immediately following removal from the eye and prior to disinfection.

Sereine Extra Strength Daily Cleaner is intended for use each time the lenses are removed from the eye.

Sereine Extra Strength Daily Cleaner is not intended for use in the eye and must be rinsed from the lens after cleaning with either sterile saline (hydrophilic lenses) or water (hydrophobic lenses).

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

8. Technological Characteristics of the Device as Compared to the Predicate Device:

	MiraFlow	Sereine
pH	8.3	8.3
Viscosity	74 cp	74 cp
Total solids	20.6%	20.8%
Sterility	Sterile	Sterile
UV-visible spectrum		Match Miraflow

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

DESCRIPTION OF TESTS CONTAINED IN TABLE ON PREVIOUS PAGE:

1. pH

   The pH of three different lots of MiraFlow Extra Strength Daily Cleaner and three different lots of Sereine Extra Strength Daily Cleaner was obtained by using a calibrated Piccolo pH meter. The results of the three lots were averaged.

2. Viscosity

   The viscosity of the MiraFlow Extra Strength Daily Cleaner and the Sereine Extra Strength Daily Cleaner was determined using a Gilmont Falling Ball Viscometer. Three lots of each cleaner were tested and the results averaged. The Gilmont Falling Ball Viscometer was Size 2 (2-100 cps) with a stainless steel ball. The viscometer was placed in a constant temperature water bath of 25C. Approximately 5 ml of solution was placed in the viscometer and the stainless steel ball was dropped. The time for the stainless steel ball to descend through the liquid was timed with a calibrated Cole-Parmer Model #94410-20 Stop Watch. The viscosity was calculated by averaging the times for the lots of MiraFlow Extra Strength Daily Cleaner. The procedure was repeated for the lots of Sereine Extra Strength Daily Cleaner.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

DESCRIPTION OF TESTS CONTAINED IN TABLE (CONT.)

3. Total Solids

The total non-volatile solids were determined by weighing an exact amount of the finished product of MiraFlow Extra Strength Daily Cleaner in a porcelain evaporating dish. The evaporating dish had been previously weighed (empty). The dish was placed in a drying oven at 105C. The dish was dried until a constant weight was obtained. The procedure was repeated using Sereine Extra Strength Daily Cleaner. Three samples of each product were tested and the results averaged. The two products were comparable as to total non-volatile solids.

4. Sterility

MiraFlow Extra Strength Daily Cleaner is labeled as a sterile product. Sereine Extra Strength Daily Cleaner was tested for sterility by Nelson Laboratories, Inc., Salt Lake City, UT using procedures contained in USP 24. Sereine Extra Strength Daily Cleaner was tested for sterility by randomly sampling finished containers from the lot. Sereine Extra Strength Daily Cleaner was found to be sterile.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

DESCRIPTION OF TESTS CONTAINED IN TABLE (CONT).

5. UV-Visible Spectra Comparison

MiraFlow Extra Strength Daily Cleaner and Sereine Extra Strength Daily Cleaner were compared using a Shimadzu UV-visible Spectrophotometer, Model UV-160. The cleaner was placed neat in a 10 mm rectangular silica absorption cell. The reference was distilled water. The absorbance range was 0-2.5 absorbance units and the spectral range was 200-1000 nm. The spectra of the two cleaners were comparable indicating like components.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

9. Summary of Non-clinical tests

The following non-clinical tests were performed on Sereine Extra Strength Daily Cleaner. These tests were not performed on MiraFlow Extra Strength Daily Cleaner as Optikem International, Inc. does not have access to materials and data necessary to conduct these tests.

Although the non-clinical tests were not performed on MiraFlow Extra Strength Daily Cleaner for comparison, it is presumed that this product performed successfully in order to obtain pre-market approval.

A. Stability Study

The stability or shelf-life study for Sereine Extra Strength Daily Cleaner was conducted using lots stored at ambient temperature for two years. The ambient temperature was between 60 and 80 F and was recorded on a daily basis as part of the quality assurance program. Three lots of Sereine Extra Strength Daily Cleaner were tested for stability. These lots were bottled in 1 FL OZ (30 ml) plastic bottles. Bottles were capped and the caps sealed with tamper-resistant seals. Bottles were not subjected to any specific conditions as far as humidity or light. The relative humidity is recorded on a daily basis as part of the quality assurance program.

SUMMARY OF SAFETY AND EFFECTIVENESS

9. Summary of Non-clinical tests (cont).

A. Stability Study (cont).

The following characteristics of Sereine Extra Strength Daily Cleaner were monitored:

1. pH

The pH of each of three lots was taken using a calibrated Piccolo pH meter. The result was compared to the original pH obtained as part of the finished device acceptance standards from the original bottling date. The pH was not changed from the time of original bottling and storage.

2. Viscosity

The viscosity of each of three lots was measured using a Gilmont Size 2 Falling Ball Type Viscometer. The viscosity of the stored lots was comparable to the viscosity as determined at the time of bottling.

3. Active Ingredients

The ingredients were determined using a Shimadzu UV-visible Spectrophotometer, Model 160 with matched silica absorption cells. Three stored lots were measured in a scan of 200-800 nm. Although the UV-visible scan was not performed on the lots as part of the original finished device acceptance, the scans were compared to a recently formulated batch. The ingredients were the same as at the beginning of the storage period as indicated by the UV-visible spectra.

K011561

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

9. Summary of Non-clinical tests (cont.)

A. Stability Study (cont.)

4. Physical Appearance

Physical appearance of the bottle, tip and cap was observed. Packaging components were examined for discoloration, cracks, and brittleness. The Sereine Extra Strength Daily Cleaner itself was observed for any precipitates, turbidity or color change. No changes in either the packing components nor the chemical components were noted.

5. Sterility

The sterility of the stored solution was tested using USP methodology by Nelson Laboratories, Inc., Salt Lake City, UT. All three stored lots tested were sterile.

6. Preservative Effectiveness with 14 day re-challenge

Preservative effectiveness testing of three stored lots was performed by Northview Pacific Laboratories, Inc. of Hercules, CA. The testing was conducted according to the FDA Guidelines contained in "Premarket Notification (510(k)) Guidance Document For Contact Lens Care Products". The stored lots passed the requirements for this test.

Conclusion:

Shelf-life studies indicated that the Sereine Extra Strength Daily Cleaner is safe and effective for the period of the proposed shelf-life of two years.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

9. Summary of Non-clinical tests (cont.)

B. Chemistry

1. Solution Compatibility

The compatibility of Sereine Extra Strength Daily Cleaner with soft (hydrophilic) lenses and hard (PMMA) lenses was demonstrated by performing the "Solution Compatibility Test" as outlined in the "Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products". Ten lenses of Metrotint (enhancing tints of polymacon, 38% water) and ten lenses of Horizon 55 (visibility tints of 55% water) were used to test solution compatibility of hydrophilic lenses. Metrotint lenses are manufactured by Metro Optics, Austin, TX. Horizon 55 lenses are manufactured by Westcon Contact Lenses, Grand Junction, CO. Ten PMMA lenses were also tested for compatibility with Sereine Extra Strength Daily Cleaner. These were blue lenses manufactured by Lens Dynamics, Lakewood, CO. The lens blanks were manufactured by Optikem Polymers of Englewood, CO.

The optical parameters were recorded before the test. Lenses were inspected for any physical defects. For hydrophilic lenses, each lens was flexed and then cleaned with Sereine Extra Strength Daily Cleaner as per product directions. After rinsing with sterile saline, the lenses were placed in a lens case and disinfected with Opti-One Solution (Alcon Laboratories, Ft Worth, TX) as per label instructions. After disinfection the lenses were removed from the lens case and the cycle repeated.The procedure was repeated for 30 cycles for each lens. After the 30 cycles, the lens parameters and physical appearance of the lenses were again recorded.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

9. Summary of Non-clinical tests (cont.)

B. Chemistry (cont.)

1. Solution Compatibility

For PMMA lenses, the lenses were cleaned with Sereine Extra Strength Daily Cleaner as per label directions. The lenses were rinsed with water and placed in lens cases. The lenses were disinfected with Sereine Wetting & Soaking Solution as per label directions. After disinfection, the lenses were removed from the lens cases and the cycle repeated. After 30 cycles, the parameters and physical appearance of the lenses were recorded and compared to those obtained prior to testing.

No significant changes in optical parameters or physical appearance was noted. Sereine Extra Strength Daily Cleaner can be used safely with hydrophilic and PMMA lenses.

2. Cleaning Effectiveness

The Determination of the critical micelle concentration of the surfactant and the surface tension of the solution done according to the procedure contained in "Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products", Appendix B. The test was conducted by SGS US Testing Company, Inc. of Passaic, NJ.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

9. SUMMARY OF NON-CLINICAL TESTS (CONT.)

C. Microbiological Tests

1. Sterility

Sterility of Sereine Extra Strength Daily Cleaner was confirmed using USP methodology.
Sterility testing of the product was done by Nelson Laboratories, Salt Lake City, UT. All lots tested were sterile. The manufacturing process used by Optikem International, Inc. to produce Sereine Extra Strength Daily Cleaner was adequate to ensure that the solution was sterile.

2. Preservative Effectiveness with 14 day rechallenge

Preservative effectiveness testing was conducted according to the procedure outlined in "Pre-market Notification (510(k)) Guidance Document for Contact Lens Care products".
The testing was conducted by Northview Pacific Laboratories, Hercules, CA.
Sereine Extra Strength Daily Cleaner passed the test for preservative effectiveness and is safe for use in a multi-dose container.

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

10. Conclusions

Based on the data outlined on the preceding pages, Sereine Extra Strength Daily Cleaner is safe and effective for use as a daily cleaner for the removal of accumulated film, deposits and debris from soft (hydrophilic) and hard (PMMA) lenses. The expiration date of two years from date of bottling is appropriate based on data outlined on the preceding pages.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2001

Ms. Sally Cook
President, Optikem International, Inc.
Wilsa, Incorporated
2172 South Jason Street
Denver, CO 80223

Re: K011561
Trade/Device Name: Sereine Extra Strength Daily Cleaner
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN; HPX
Dated: October 1, 2001
Received: October 2, 2001

Dear Ms. Cook:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K011561

NOV 2 0 2001

INDICATIONS FOR USE STATEMENT

Sereine Extra Strength Daily Cleaner is indicated for use as a daily cleaner for removal of film, deposits and other debris which accumulate on soft (hydrophilic) and PMMA contact lenses during wear.

Sereine Extra Strength Dailly Cleaner may be used with either thermal (heat) or chemical (cold) disinfection systems. Follow the recommendation of your eye care practitioner when disinfecting your lenses.

Ph.D

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011561

Over-the-Counter Use ✓